APPENDIX A

United States Court of Appeals for the Federal Circuit

In re CRUCIFEROUS SPROUT LITIGATION.

Brassica Protection Products LLC and Johns Hopkins University,

Plaintiffs-Appellants,

v.

Sunrise Farms, Becky Crikelair, and Frank Crikelair,

Defendants-Appellees,

and

Edrich Farms Inc., Edward B. Stanfield, III, Edward F. Stanfield, Jr., Richard Stanfield, and Sally F. Stanfield,

Defendants-Appellees,

and

Banner Mountain Sprouts, Banner Mountain Sprouts Inc., and Lawrence Ravitz,

Defendants-Appellees,

and

Harmony Farms, Greg Lynn, and Lorna Lynn,

and

International Specialty Supply and Robert L. Rust,

Defendants-Appellees.

No. 02-1031

Argued: May 9, 2002

DECIDED: Aug. 21, 2002.

Affirmed.

Before CLEVENGER, BRYSON, and PROST, Circuit Judges.

PROST, Circuit Judge.

Brassica Protection Products LLC and Johns Hopkins University (collectively "Brassica") appeal from the decision of the United States District Court for the District of Maryland granting summary judgment that U.S. Patent Nos. 5,725,895 ("the '895 patent"), 5,968,567 ("the '567 patent"), and 5,968,505 ("the '505 patent") are invalid as anticipated by the prior art. *In re Cruciferous Sprout Patent Litig.*, 168 F. Supp. 2d 534, 60 USPQ.2d 1758 (D. Md. 2001). We affirm the district court's ruling.

BACKGROUND

The three patents-in-suit relate to growing and eating sprouts to reduce the level of carcinogens in animals, thereby reducing the risk of developing cancer. Specifically, the patents describe methods of preparing food products that contain high levels of substances that induce Phase 2 enzymes. These enzymes are part of the human body's mechanism for detoxifying potential carcinogens. Thus, they have a chemoprotective effect against cancer. '895 patent, col. 1, ll. 28-34. Foods that are rich in glucosinolates, such as certain cruciferous sprouts, have high Phase 2 enzyme-inducing potential. The inventors of the patents-in-suit recognized that the Phase 2 enzyme-inducing agents (or their glucosinolate precursors) are far more concentrated in certain sprouts (such as broccoli and cauliflower but not cabbage, cress, mustard or radish) that are harvested before the two-leaf stage than in corresponding adult plants. *Id.* at col. 7, l. 63 - col. 8, l. 14. However, glucosinolate levels in cruciferous plants can be highly variable. *See id.* at col. 12, ll. 66-67 ("There is variation in inducer potential among different broccoli cultivars."). According to the inventors, it is there-

fore desirable to select the seeds of those cruciferous plants which, when germinated and harvested before the two-leaf stage, produce sprouts that contain high levels of the desired enzyme-inducing potential.

The '895 patent was filed on September 15, 1995, and claims, *inter alia*, "A method of preparing a food product rich in glucosinolates, comprising germinated cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds, and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts." '895 patent, claim 1. The '567 patent is a continuation of the '895 application and it claims a "method of preparing a human food product" from sprouts. '567 patent, claims 1 and 9. The '505 patent is a divisional of the '895 application and it claims a "method of increasing the chemoprotective amount of Phase 2 enzymes in a mammal," as well as a "method of reducing the level of carcinogens in a mammal," by creating a "food product" from sprouts and then "administering said food product" to a mammal. '505 patent, claims 1 and 16.

The three patents-in-suit are owned by Johns Hopkins University and exclusively licensed to Brassica Protection Products LLC. Johns Hopkins and Brassica sued Sunrise Farms, Becky Crikelair, Frank Crikelair, Edrich Farms, Inc., Edward B. Stanfield, III, Edward F. Stanfield, Jr., Richard Stanfield, Sally F. Stanfield, Banner Mountain Sprouts, Banner Mountain Sprouts, Inc., Lawrence Ravitz, Harmony Farms, International Specialty Supply, Greg Lynn, Lorna Lynn and Robert L. Rust (collectively "defendants") in various district courts. Pursuant to 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation consolidated the various cases in the District of Maryland for pretrial proceedings. On June 7, 2001, the defendants filed a joint motion for partial summary judgment of invalidity, arguing that the patents were anticipated by prior art references

disclosing growing and eating sprouts. Brassica filed a cross-motion for summary judgment that the patents are not invalid. On July 23, 2001, the district court held a *Markman* hearing to address claim construction issues and the parties' motions for summary judgment.

On August 10, 2001, the court granted defendants' motion for summary judgment of invalidity and denied Brassica's cross-motion for summary judgment. According to the district court, "[t]he record before the Court makes it abundantly clear that, prior to the issuance of the patents-in-suit, one skilled in the art could, by following the teachings of the prior art, germinate broccoli seeds, harvest the sprouts, and sell them as a food product." *In re Cruciferous Sprout Patent Litig.*, 168 F. Supp. 2d at 540, 60 USPQ.2d at 1762. While recognizing that the inventors of the patents-in-suit may have discovered a new and significant property of certain types of cruciferous sprouts, the district court concluded that "merely describing unexpected beneficial results of a known process does not entitle Plaintiffs to patent that process." *Id.* at 538, 60 USPQ.2d at 1760. Thus, a "plant (broccoli sprouts), long well known in nature and cultivated and eaten by humans for decades, [cannot] be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature." *Id.* at 537, 60 USPQ.2d at 1759. On October 1, 2001, the court entered a Judgment Under Rule 54(b) in favor of defendants but limited its invalidity ruling to claims 1-6 and 9 of the '895 patent, claims 1-8 of the '567 patent, and claims 1 and 16 of the '505 patent. *In re Cruciferous Sprout Patent Litig.*, MDL Docket No. 1388 (D. Md. Oct. 1, 2001) (Rule 54(b) Determination). Brassica appeals the judgment of invalidity, arguing that the district court failed to properly construe the claims and did not apply the properly construed claims to the prior art when determining that the claims are anticipated under 35 U.S.C. § 102(b). We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

This court reviews a grant of summary judgment *de novo*, drawing all reasonable factual inferences in favor of the non-moving party. *See, e.g., Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L. Ed. 2d 202 (1986). Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Id.* at 247-48. Anticipation is a question of fact, *Gen. Elec. Co. v. Nintendo Co.*, 179 F.3d 1350, 1353, 50 USPQ.2d 1910, 1912 (Fed. Cir. 1999), and is determined by first construing the claims and then comparing the properly construed claims to the prior art, *Gechter v. Davidson*, 116 F.3d 1454, 1457, 43 USPQ.2d 1030, 1032 (Fed. Cir. 1997). Claim construction is an issue of law that we review *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456, 46 USPQ.2d 1169, 1174 (Fed. Cir. 1998) (en banc). We also determine *de novo* whether the evidence in the record raises any genuine disputes about material facts. *Gen. Elec.*, 179 F.3d at 1353, 50 USPQ.2d at 1912.

I.

Brassica contends that the district court erroneously construed the claims by failing to treat the preamble of claim 1 of the '895 patent as a limitation of the claims. In addition, Brassica argues that the district court failed to construe the limitations "rich in glucosinolates" (appearing in claims 1 and 9 of the '895 patent) and "high Phase 2 enzyme-inducing potential" (appearing in claim 1 of the '567 patent and claims 1 and 16 of the '505 patent).

No litmus test defines when a preamble limits claim scope. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ.2d 1962, 1966 (Fed. Cir. 1989). Whether to treat a preamble as a limitation is a determination "resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Id.*;

Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ.2d 1781, 1785 (Fed. Cir. 2002). In general, a preamble limits the claimed invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. *Catalina Mktg.*, 289 F.3d at 808, 62 USPQ.2d at 1784 (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ.2d 1161, 1165 (Fed. Cir. 1999)). Clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art may indicate that the preamble is a claim limitation because the preamble is used to define the claimed invention. *Catalina Mktg.*, 289 F.3d at 808, 62 USPQ.2d at 1785; *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375, 58 USPQ.2d 1508, 1513 (Fed. Cir. 2001).

In this case, both the specification and prosecution history indicate that the phrase "rich in glucosinolates" helps to define the claimed invention and is, therefore, a limitation of claim 1 of the '895 patent. The specification, for example, states that "this invention relates to the production and consumption of foods which are rich in cancer chemoprotective compounds." '895 patent, col. 1, ll. 18-19. A stated object of the invention is "to provide food products and food additives that are rich in cancer chemoprotective compounds." *Id.* at col. 2, ll. 38-39. The specification therefore indicates that the inventors believed their invention to be making food products that are rich in chemoprotective compounds, or, in other words, food products "rich in glucosinolates."[1] In addition, during reexamination[2] of the '895

[1] Phase 2 enzymes are part of the human body's mechanism for detoxifying potential carcinogens. These enzymes therefore have a chemoprotective effect against cancer. According to the '895 patent, "most of the [Phase 2 enzyme] inducer potential of crucifer plants is due to their content of isothiocyanates and their biogenic precursors, glucosinolates." '895 patent, col. 8, ll. 14-16.

patent the patentee argued as follows:

> Claim 1 of the patent, for example, is directed to "[a] method of preparing a food product rich in glucosinolates, ... and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts." ... Although "rich in glucosinolates" is recited in the preamble of the claim, the pertinent case law holds that the preamble is given weight if it breathes life and meaning into the claim.... Accordingly, the cited prior art does not anticipate the claims because it does not explicitly teach a method of preparing a food product comprising cruciferous sprouts that are rich in glucosinolates or contain high levels of Phase 2 inducer activity.

This language shows a clear reliance by the patentee on the preamble to persuade the Patent Office that the claimed invention is not anticipated by the prior art. As such, the preamble is a limitation of the claims. *See Bristol-Myers Squibb*, 246 F.3d at 1375, 58 USPQ.2d at 1513.

Brassica also asks this court to construe the phrases "rich in glucosinolates" and "high Phase 2 enzyme-inducing potential" to require "at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential at 3-days

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[2] On December 6, 1999, the Patent Office granted a request for reexamination of the '895 patent. Claims 1-6 and 9-13 were rejected as anticipated by or obvious in light of many of the same prior art references relied on by the defendants in this case. After considering the patentee's arguments and declarations in support of patentability, the Patent Office issued a reexamination certificate and gave the following examiner's statement of reasons for patentability: "a method of preparing a food product wherein cruciferous sprouts, with the exception of cabbage, cress, mustard, and radish sprouts, that are rich in glucosinolates or contain high levels of phase 2 inducer activity are harvested prior to the 2-leaf stage is not taught or fairly suggested by the prior art or any combination thereof."

following incubation under conditions in which cruciferous seeds germinate and grow." '895 patent, col. 7, ll. 47-53.

"[T]he words of a claim are generally given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor." *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1577, 27 USPQ.2d 1836, 1840 (Fed. Cir. 1993). However, "limitations appearing in the specification will not be read into claims, and ... interpreting what is *meant* by a word *in* a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.'" *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053, 12 USPQ.2d 1474, 1476 (Fed. Cir. 1989). Brassica's proposed construction violates this rule by improperly importing limitations from the specification into the claims. True, the specification states that "[s]uitable sprouts will have at least 200,000 units per gram of fresh weight of Phase 2 enzyme-inducing potential following 3-days incubation of seeds under conditions in which the seeds germinate and grow." '895 patent, col. 10, l. 66 - col. 11, l. 2. The specification does not, however, indicate that the phrases "rich in glucosinolates" or "high in Phase 2 enzyme-inducing potential" are limited to these precise conditions. Rather, the specification uses the term "high" in its ordinary, comparative sense to mean "not low." For example, the specification states that "[t]he cruciferous sprouts of the instant invention have higher Phase 2 enzyme-inducer potential than market stage plants," *id.* at col. 14, ll. 5-7, and the "Phase 2 enzyme-inducing potential of such sprouts may be as much as several hundred times higher than that observed in adult, market stage vegetables obtained from the same seeds," *id.* at col. 8, ll. 6-9; *see also Innovad Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1332, 59 USPQ.2d 1676, 1680 (Fed. Cir. 2001) (construing the term "small volume" based in part on the specification's use of the phrase in its general sense to mean "not large"). Likewise, the term "rich" is not specifi-

cally defined or limited by the specification, but instead is used in its ordinary, relative sense. *See, e.g., id.* at col. 11, ll. 15-17 ("Mature Brussels sprouts and rapeseed are rich in these undesirable glucosinolates."); col. 11, ll. 37-39 ("Seeds, as well as sprouts have been found to be extremely rich in inducer potential.").

Brassica's proposed construction is also inconsistent with the language of the dependent claims. Claim 19 of the '567 patent recites: "The method according to claim 1, wherein said seeds produce cruciferous sprouts containing at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential measured after 3-days of growth." '567 patent, col. 22, ll. 62-65. Brassica's proposed construction would render this claim meaningless. *See Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187, 48 USPQ.2d 1001, 1005-06 (Fed. Cir. 1998) (finding a violation of the doctrine of claim differentiation when a proposed construction would render another claim superfluous). We therefore reject Brassica's proposed claim construction for the phrases "rich in glucosinolates" and "high in Phase 2 enzyme-inducing potential."

II.

Having construed the claim limitations at issue, we now compare the claims to the prior art to determine if the prior art anticipates those claims. In order to prove that a claim is anticipated under 35 U.S.C. § 102(b), defendants must present clear and convincing evidence that a single prior art reference discloses, either expressly or inherently, each limitation of the claim. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565, 24 USPQ.2d 1321, 1326 (Fed. Cir. 1992).

Brassica argues that the prior art does not expressly or inherently disclose the claim limitations of "preparing a food product rich in glucosinolates" (claims 1 and 9 of the '895 patent), or "identifying seeds which produce cruciferous

sprouts ... containing high Phase 2 enzyme-inducing potential" (claims 1 and 16 of the '505 patent, claim 1 of the '567 patent). According to Brassica, the prior art merely discusses growing and eating sprouts without mention of any glucosinolates or Phase 2 enzyme-inducing potential, and without specifying that particular sprouts having these beneficial characteristics should be assembled into a "food product."[3] Moreover, Brassica argues, the prior art does not inherently disclose these limitations because "at most, one following the prior art would have a possibility or probability of producing a food product high in Phase 2 enzyme-inducing potential" and the "fact that one following the prior art might have selected seeds meeting the limitations of the claims is not sufficient to establish inherent anticipation."

It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. *See, e.g., Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 51 USPQ.2d 1943 (Fed. Cir. 1999); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 USPQ.2d 1303, 1305 (Fed. Cir. 1999) (finding anticipation of a method of hair depilation by an article teaching a method of skin treatment but recognizing the disruption of hair follicles, citing *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986)). "Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the

[3] "A food product is any ingestible preparation containing the sprouts of the instant invention, or extracts or preparations made from these sprouts ...." '895 patent, col. 6, ll. 26-28.

prior art." *MEHL/Biophile*, 192 F.3d at 1365, 52 USPQ.2d at 1305-06; *Atlas Powder*, 190 F.3d at 1347, 51 USPQ.2d at 1946-47.

Brassica does not claim to have invented a new kind of sprout, or a new way of growing or harvesting sprouts. Rather, Brassica recognized that some sprouts are rich in glucosinolates and high in Phase 2 enzyme-inducing activity while other sprouts are not. *See* '895 patent, col. 10, ll. 28-42 ("Sprouts suitable as sources of cancer chemoprotectants are generally cruciferous sprouts, with the exception of cabbage (Brassica olecracea capitata), cress (Lepidiumsativum), mustard (Sinapis alba and S. niger) and radish (Raphanus sativus) sprouts."). But the glucosinolate content and Phase 2 enzyme-inducing potential of sprouts necessarily have existed as long as sprouts themselves, which is certainly more than one year before the date of application at issue here. *See, e.g.*, Karen Cross Whyte, *The Complete Sprouting Cookbook* 4 (1973) (noting that in "2939 B.C., the Emperor of China recorded the use of health giving sprouts"). Stated differently, a sprout's glucosinolate content and Phase 2 enzyme-inducing potential are inherent characteristics of the sprout. *Cf.* Brian R. Clement, *Hippocrates Health Program* 8 (1989) (referring to "[i]nherent enzyme inhibitors, phytates (natural insecticides), oxalates, etc., present in every seed"). It matters not that those of ordinary skill heretofore may not have recognized these inherent characteristics of the sprouts. *MEHL/Biophile*, 192 F.3d at 1365, 52 USPQ.2d at 1305.

Titanium Metals Corp. v. Banner is particularly instructive in this regard. In that case, the claim at issue recited:

> A titanium base alloy consisting essentially by weight of about 0.6% to 0.9% nickel, 0.2% to 0.4% molybdenum, up to 0.2% maximum iron, balance titanium, said alloy being characterized by good corrosion resistance in hot brine environments.

Titanium Metals, 778 F.2d at 776, 227 USPQ at 774. The prior art disclosed a titanium base alloy having the recited components of the claim, but the prior art did not disclose that such an alloy was "characterized by good corrosion resistance in hot brine environments." We nevertheless held that the claim was anticipated by the prior art, because "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." *Id.* at 782, 774 F.2d 483, 227 USPQ at 779. *Titanium Metals* explained the rationale behind this common sense conclusion:

> The basic provision of Title 35 applicable here is § 101, providing in relevant part: "Whoever invents or discovers any new ... composition of matter, or any new ... improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."....
>
> ... [C]ounsel never came to grips with the real issues: (1) what do the claims cover and (2) is what they cover new? Under the laws Congress wrote, they must be considered. Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties, or has found out to what extent one can modify the composition of the alloy without losing such properties.

Id. at 780, 782, 778 F.2d 775, 227 USPQ at 777-78. Brassica has done nothing more than recognize properties inherent in certain prior art sprouts, just like the corrosion resistance properties inherent to the prior art alloy in *Titanium*

Metals.[4] While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new.

Brassica nevertheless argues that its claims are not anticipated because the prior art does not disclose selecting the particular seeds that will germinate as sprouts rich in glucosinolates and high in Phase 2 enzyme-inducing potential (as opposed to selecting other kinds of seeds to sprout) in order to form a food product. We disagree. The prior art teaches sprouting and harvesting the very same seeds that the patents recognize as producing sprouts rich in glucosinolates and having high Phase 2 enzyme-inducing potential. According to the patents, examples of suitable sprouts are

> typically from the family Cruciferea, of the tribe Brassiceae, and of the subtribe Brassicinae. Preferably the sprouts are Brassica oleracea selected from the group of varieties consisting of acephala (kale, collards, wild cabbage, curly kale), medullosa (marrow-stem kale), ramosa (thousand head kale), alboglabra (Chinese kale), botrytis (cauliflower, sprouting broccoli), costata (Portugese kale), gemmifera (Brussels sprouts), gongylodes (kohlrabi), italica (broccoli), palmifolia (Jersey kale), sabauda (savoy cabbage), sabellica (collards), and selensia (borecole), among others.

'895 patent, col. 10, ll. 32-42. Numerous prior art references identify these same sprouts as suitable for eating. *See, e.g.*,

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[4] Most of the claims at issue are method claims, not composition or product claims. Nevertheless, the principles of *Titanium Metals* still apply. *See, e.g.*, *MEHL/Biophile*, 192 F.3d at 1366-67, 52 USPQ.2d at 1306 (finding anticipation by inherency of a method of hair depilation); *Bristol-Myers*, 246 F.3d at 1376, 58 USPQ.2d at 1514 (Fed. Cir. 2001) (stating that "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent").

Stephen Facciola, *Cornucopia: A Source Book of Edible Plants* 47 (1990) (listing "Brassica oleracea Botrytis Group Cauliflower ... Sprouted seeds are eaten"), Esther Munroe, *Sprouts to Grow and Eat* 9-14 (1974) (identifying "Broccoli, Brussels sprouts, Cabbage, Cauliflower, Collards and Kale"). These references therefore meet the claim limitation of identifying seeds to use in order to have sprouts with the inherent properties of glucosinolates and high Phase 2 enzyme-inducing activity. Despite the patents' admissions about the suitability of particular plant species found in these prior art references, Brassica argues that only specific cultivars of these plant species are rich in glucosinolates and high in Phase 2 enzyme-inducing activity. Thus, according to Brassica, the prior art fails to meet the "identifying" steps of the claims because it does not specify which cultivars should be sprouted. However, all of the appropriate cultivars that are identified in Brassica's patent are in the public domain. '895 patent, col. 10, ll. 43-65. Brassica cannot credibly maintain that no one has heretofore grown and eaten one of the many suitable cultivars identified by its patents. It is unnecessary for purposes of anticipation for the persons sprouting these particular cultivars to have realized that they were sprouting something rich in glucosinolates and high in Phase 2 enzyme-inducing potential. *Atlas Powder*, 190 F.3d at 1348, 51 USPQ.2d at 1947 ("The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup of the underlying scientific principles which allow them to operate.").

The prior art also discloses the remaining limitations of the claims. The Munroe reference, for example, recommends that sprouts be harvested between "3 to 5 days for a sprouted length of 1/2 to 1 inch." Munroe at 9. Photographs of these sprouts show that they have not yet reached the two-leaf stage of development. *Id.* at 10-13. Thus, this reference discloses the claim limitations of germinating the appropriate

cruciferous seeds and harvesting the resulting sprouts prior to the 2-leaf stage. *See* '895 patent, claims 1 and 9; '567 patent, claims 1 and 2; '505 patent, claims 1 and 16. Munroe also discloses that these particular sprouts can be used in food products such as "soups, salads and main dishes," *id.* at p. 14, thereby meeting the claim limitation of forming a food product comprising a plurality of the sprouts ('895 patent claims 1 and 9; '567 patent, claims 1 and 8; '505 patent, claims 1 and 16) and the claim limitation of administering (eating) the food product ('505 patent, claims 1 and 16). The Munroe reference therefore discloses each and every limitation of these claims of the patents. *See also*, Meyerowitz, *Growing Vegetables Indoors* (1990).

In summary, the prior art inherently contains the claim limitations that Brassica relies upon to distinguish its claims from the prior art. While Brassica may have recognized something about sprouts that was not known before, Brassica's claims do not describe a new method.

CONCLUSION

For the foregoing reasons, we affirm the district court's summary judgment that the claims at issue are anticipated by the prior art. The prior art indisputably includes growing, harvesting and eating particular sprouts which Brassica has recognized as being rich in glucosinolates and high in Phase 2 enzyme-inducing potential. But the glucosinolate content and Phase 2 enzyme- inducing potential of these sprouts are inherent properties of the sprouts put there by nature, not by Brassica. Brassica simply has not claimed anything that is new and its claims are therefore invalid.

AFFIRMED

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CIVIL ACTION NO: MDL 1388.

In re CRUCIFEROUS SPROUT PATENT LITIGATION.

August 8, 2001

MEMORANDUM

NICKERSON, District Judge.

Pursuant to 28 U.S.C. § 1407, the Judicial Panel for Multidistrict Litigation consolidated these actions before this Court for pre-trial purposes. These actions all involve the validity of certain patents owned by Plaintiffs Brassica Protection Products LLC and Johns Hopkins University. On July 23, 2001, the Court held a Markman[5] hearing addressing the construction of the claims at issue, and also heard argument on Defendants' Motion for Summary Judgment, which had been fully briefed.[6] Upon consideration of the pleadings, the argument of counsel, and the relevant case law, the Court determines that Defendants' motion should be granted.

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[5] *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L. Ed. 2d 577 (1996).

[6] Also pending is Plaintiffs' Cross Motion for Summary Judgment. Although Defendants vehemently disagreed with this characterization at the hearing, Plaintiffs' motion, for the most part, does represent the mirror image of the issues raised in Defendants' motion. Thus, the Court has considered the briefing of Plaintiffs' motion in reaching the instant decision.

I. FACTUAL AND PROCEDURAL BACKGROUND

The patents-in-suit all involve the production and the consumption of the sprouts of certain types of cruciferous seeds such as broccoli and cauliflower. The inventors of the patents, Jed Fahey and Paul Talalay, discovered that the sprouts of these seeds, when harvested and consumed at a particular stage of their growth, contain high Phase 2 enzyme-inducing potential and non-toxic levels of indole glucosinolates. These substances aid the body's natural cancer fighting defense mechanisms.

Although all three patents-in-suit relate to cruciferous sprouts and glucosinolates, each varies slightly in its emphasis. Patent 5,725,895 discloses and claims, *inter alia*, "a method of preparing a food product rich in glucosinolates, comprising germinated cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds,[7] and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts." '895 patent, claim 1. Patent 5,968,567 discloses and claims, *inter alia*, a method of preparing a human food product comprising cruciferous sprouts containing high Phase 2 enzyme-inducing potential and non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates. '567 patent, claim 1. The '567 patent also specifies the steps of the invention as "(a) identifying seeds which produce said sprouts ... (b) germinating said seeds; and (c) harvesting said spouts between the onset of germination up to and including the 2-leaf stage, to form a human food product." *Id.* The last patent-in-suit, Patent 5,968,505, claims "a method of increasing the chemoprotective amount

[7] The inventors discovered that while the sprouts of some cruciferous seeds, such as broccoli and cauliflower, contain high levels of glucosinolates, other cruciferous seeds, such as cabbage, cress, mustard and radish, do not contain the same concentration of that substance.

of Phase 2 enzymes in a mammal." '505 patent, claim 1. The '505 patent then recites the three steps of the '567 patent, and adds a fourth: "(d) administering said food product, or a non-toxic extract of said food product, to said animal."

Plaintiffs' sprouts have been the subject of litigation prior to the instant suits. In June of 1999, Plaintiff Brassica filed an action in the United States District Court for the District of Delaware against Sproutman, Inc. and Murray Tiser (collectively, Sproutman), alleging that these defendants were infringing on the '895 patent[8] by producing and selling broccoli sprouts. Civ. Action No. 99-350-SLR. Sproutman argued in that litigation that the '895 patent was invalid under 35 U.S.C. § 102(b), because the patent was anticipated by the prior art and was invalid as obvious under 35 U.S.C. § 103. This prior art reveals that it has been well known for years that broccoli seeds can be sprouted and the sprouts consumed as food.

During the pendency of the Delaware litigation, Sproutman also filed a request for reexamination with the U.S. Patent and Trademark Office. The Patent Office granted Sproutman's request and issued an Office Action in Reexamination, rejecting Claims 1-6 and 9-13 of the '895 patent, finding these claims both anticipated under § 102(b) and unpatentable under § 103. Brassica then filed an Amendment and Request for Reconsideration, raising essentially the same arguments that Plaintiffs raise here. Upon reconsideration, the Patent Office withdrew the rejections and re- affirmed the validity of Claims 1-6 and 9-13.

Referencing the prior art submitted in the re-examination proceedings, as well as some additional published sources that pre-date Plaintiffs' patents, Defendants argue in the

[8] At the time this suit was filed, the '567 and '505 patents had not been issued.

pending summary judgment motion that Plaintiffs' patents are invalid because the "invention" is not "new." As Defendants succinctly present the question before the Court: "Can a plant (broccoli sprouts), long well known in nature and cultivated and eaten by humans for decades, be patented merely on the basis of a recent realization that the plant has always had some heretofore unknown but naturally occurring beneficial feature?" Defendants' June 7, 2001 Supplemental Memo. at 1 (emphasis in original). For the reasons that follow, the Court finds that the answer to that question must be "no."

II. LEGAL STANDARD

Summary judgment is appropriate when, based on the record before the Court, no genuine issue exists as to any material fact, and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c). A genuine issue exists if the evidence is such that a reasonable jury could find for the nonmoving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986); *General Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 980 (Fed. Cir. 1997). A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *See Anderson*, 477 U.S. at 248, 106 S.Ct. 2505; *General Mills*, 103 F.3d at 980.

Under the patent statutes, a patent enjoys a presumption of validity, see 35 U.S.C. § 282 (1994), which can be overcome only through clear and convincing evidence. *See United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1563 (Fed. Cir. 1997). Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable finder of fact could conclude otherwise. In determining whether a genuine issue of material fact exists, the court views the evidence in the light most favorable to the

nonmoving party and resolves all doubts in its favor. *See Anderson*, 477 U.S. at 255, 106 S.Ct. 2505; *Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274 (Fed. Cir. 1995).

III. DISCUSSION

The facts relevant to the construction and the validity of Plaintiffs' patent claims are fairly uncomplicated and largely undisputed. Plaintiffs do not dispute that the prior art taught that cruciferous seeds, including broccoli, can be germinated and consumed as a food product in the sprout stage.[9] *See, e.g.*, Esther Munroe, *Sprouts to Grow and Eat*, 9-14 (Second printing Dec. 1977) (1974) ("CABBAGE FAMILY—Broccoli ... Cauliflower ... and Kale.... All are easy to sprout and each one produces a tasty sprout .... these sprouts tend to be strong flavored or bitter if grown too long, so use them when they are most pleasant to your taste in soups, salads and main dishes. Like their parent plants they are high in vitamins and so are well worth sprouting"); Stephen Facciola *Cornucopia: A Source Book of Edible Plants*, 47 (1990). Plaintiffs also do not claim that their patents involve doing anything to alter or modify the natural seeds. They are simply germinated, harvested, and eaten.

Defendants, on the other hand, do not dispute that Fahey and Talalay discovered a new and significant property of certain types of cruciferous sprouts, *i.e.*, that these sprouts

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[9] Plaintiffs' counsel represented at the hearing that, while the prior art may have described how cruciferous seeds could be grown into sprouts for food, few if any individuals were actually producing, marketing, or consuming broccoli sprouts until September 1997 when Fahey and Talalay published their findings regarding the beneficial health properties of those sprouts. Assuming that this representation is accurate, it makes no difference to the question before the Court. Invalidity by anticipation requires only that the prior art discloses to one of skill in the art how to do a thing, it does not matter if it was ever done. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001).

contain high levels of substances that aid the human body in preventing cancer. Defendants do not challenge that Fahey and Talalay also discovered that certain cruciferous sprouts, such as broccoli and cauliflower, contain much higher levels of these substances than other cruciferous seeds. Instead, Defendants contend, and the Court agrees, that merely describing unexpected beneficial results of a known process does not entitle Plaintiffs to patent that process.

It is a fundamental precept of patent law that a product is not patentable unless it is new. Patent claims that lack novelty are said to be anticipated by the prior art and are invalid pursuant to 35 U.S.C. § 102(b). Section 102(b) provides that a patent is invalid as anticipated if the claimed invention "was patented or described in a printed publication in this or a foreign country or in public use or on sale in the country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Courts have interpreted § 102(b) to require that "each and every element as set forth in the claim [be] found, either expressly *or inherently* described, in a single prior art reference." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) (emphasis added).

Under the concept of inherency, where the prior art necessarily functions in accordance with or includes the claimed limitations, the prior art anticipates those limitations. *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986). It is important to note that a property or result can be inherent in the prior art regardless of whether those skilled in the art were previously aware of that property or result. "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342 (Fed. Cir. 1999). "However, the discovery of a previously unappreciated property of a prior art composition ... does not render the old composition patentably new to the discoverer." *Id.*

These principles were applied by the Federal Circuit Court of Appeals in *Titanium Metals Corp. of Amer. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). In *Titanium Metals*, the patent applicants sought to obtain a patent for an alloy made up of titanium and small percentages of nickel, molybdenum, and iron. The applicants had discovered that titanium alloys within a specified range were characterized by good corrosive resistance in hot brine environments. The patent examiner, as well as the Patent and Trademark Office Board of Appeals, rejected their patent application, however, on the ground, *inter alia*, that the claims were anticipated by an article published in a Russian journal of metallurgy five years prior to the filing date of the application. The applicant appealed the Patent Board's decision and the district court reversed, ordering the Commissioner to authorize the patent. The Commissioner then appealed and the Federal Circuit Court reversed the district court's decision, reaffirming the conclusion of the Patent Office that the patent was anticipated by the prior art.

There was no dispute in *Titanium Metals* that the referenced Russian journal article described a range of titanium-nickel-molybdenum alloys that included the alloys sought to be patented. The patent applicants and the district court concluded that the claims were not anticipated by the prior art, however, because the corrosive resistant properties of the selected alloys were not disclosed in the Russian article. In reversing, the Federal Court observed,

> As we read the situation, the [district] court was misled by the arguments and evidence to the effect that the inventors here found out and disclosed in their application many things that one cannot learn from reading the Russian article and that this was sufficient in law to justify granting them a patent for their contributions—such things as what good corrosion resistance the claimed alloys have against hot brine, which possibly

> was not known, and the range limits of the Ni and Mo content, outside of which that resistance diminishes, which are teachings of very useful information. These things the applicants teach the art and the Russian article does not.

778 F.2d at 781.

The Federal Circuit further opined that counsel had lost sight of the real issues in the litigation: "1) what do the claims cover and 2) is what they cover new?" *Id.* at 782. "Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties, or has found out to what extent one can modify the composition of the alloy without losing such properties." *Id.*

The court also provided some helpful guidance as to the proper construction of claims where the claims purport to include descriptions of the inherent properties of a process or composition. One of the claims at issue contained the phrase, "characterized by good corrosion resistance in hot brine environment." This phase was also applied to the two dependant claims. The Federal Circuit observed that this phrase may have led the district court to improperly interpret the claims as directed to the applicants' discoveries about the properties of the alloys instead of the alloys themselves. "[T]he correct and necessary construction of all three claims [is] that they simply define titanium base alloys.... [I]t is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." *Id.* at 782.

The Federal Circuit just recently repeated much of this same teaching in ***Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.*** ***Bristol-Myers*** involved two patents related to a method of administering the antitumor drug paclitaxel over a three hour period. Bristol-Myers, the assignee of the patent,

brought an infringement action. The defendants moved for summary judgment, arguing that the patents were invalid as their claims were anticipated by the prior art, specifically an article by Mark Kris, a researcher who had treated cancer patients with three hour infusions of paclitaxel within the claimed dosage ranges. While Kris had employed that infusion method, the study was largely unsuccessful in that he did not observe any antitumor response. Kris also recommended premedication regimens as a possible means to minimize hypersensitivity reactions, but he did not himself employ those regimens in his study.

After a Markman hearing, the district court held that much of the preamble language in the claims describing the intended results of the treatment was non-limiting and could be ignored for the purposes of construing the claim and determining anticipation. The district court then granted the defendants' motion for summary judgment on the ground of invalidity by anticipation.

In affirming the district court's decision, at least in large part, the Federal Circuit agreed that the preamble language did not limit the claims. The court concluded that language such as "for reducing hematologic toxicity" and " 'to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity,' only states an intended result of that claimed method.... The steps of the three-hour infusion method are performed in the same way regardless whether or not the patient experiences a reduction in hematologic toxicity...." 246 F.3d at 1374-75. The court also affirmed the district court's conclusion that the patents were invalid on the basis of anticipation:

> Kris therefore performed all of the claimed steps at dosage levels that anticipate those in the claims. Although Kris did not observe any anticancer effects, we have already determined that the claims only require the administration of specific amounts of

> paclitaxel and not the achievement of a particular result.

Id at 1378. The court found that the patent claims related to premedication were also anticipated by the Kris article, even though Kris himself never followed the teaching. "[A]nticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art." *Id.* at 1379 (citing *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985)).

In construing the claims at issue here, the Court finds that they describe nothing more than germinating sprouts from certain cruciferous seeds and harvesting those sprouts as a food product, a process that was known long before the application for these patents. Phrases in the claims such as, "rich in glucosinolates," or "containing high Phase 2 enzyme potential and non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates," simply describe the inherent properties of certain cruciferous seeds, in the same way that "characterized by good corrosion resistance in hot brine environment" described the inherent property of the selected alloys in *Titanium Metal*. Similarly, the phrase, "increasing the chemoprotective amount of Phase 2 enzymes in a mammal" does nothing more than describe an intended result of a process, in the same way as the phrase, "to effect regression of a taxol-sensitive tumors" functioned in the patent at issue in *Bristol-Myers*. These phrases are plainly non- limiting.

Plaintiffs attempted in their pleadings, and at the hearing, to argue that the claim language, "identifying seeds which produce cruciferous sprouts ... containing [the desired properties]" introduces a new "selection" step that was not a part of the prior art. All this step entails, however, is choosing to do one thing over another, in this case, choosing to grow broccoli or cauliflower sprouts instead of cabbage, cress,

mustard or radish sprouts. Any process could be prefaced by a similar "selection" step. Certainly, that one first chooses to perform a particular process cannot be enough to make the process "new."

The record before the Court makes it abundantly clear that, prior to the issuance of the patents-in-suit, one skilled in the art could, by following the teachings of the prior art, germinate broccoli seeds, harvest the sprouts, and sell them as a food product. It is Plaintiffs' position that their patents now forbid Defendants from doing what they once could plainly do. Under longstanding principles of the patent law, "if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art." *Atlas Powder*, 190 F.3d at 1346 (citing *Titanium Metals*, 778 F.2d at 781)). Thus, the Court finds that the patents-in-suit are invalid by anticipation.

IV. CONCLUSION

For the above stated reasons, Defendants' Motion for Partial Summary Judgment will be granted. This decision would appear, as a practical matter, if not as a matter of law, to be dispositive of the pending actions. There was some disagreement on this issue, however, when it was raised by the Court at the hearing. Because of this uncertainly, the Court would like to hear from counsel as to what additional steps, in light of this decision, may be needed to finally resolve these actions, or to place them in a posture for appeal to the Federal Circuit. Accordingly, the Court requests that the parties confer and then submit a joint status report, on or before August 24, 2001.

A separate order will issue.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CIVIL ACTION NO: MDL 1388.

In re CRUCIFEROUS SPROUT PATENT LITIGATION.

August 8, 2001

ORDER

NICKERSON, District Judge.

In accordance with the foregoing Memorandum and for the reasons stated therein, IT IS this 8th day of August, 2001, by the United States District Court for the District of Maryland, ORDERED:

1. That Defendants' Motion for Partial Summary Judgment Regarding Invalidity of Patents in Suit, Paper No. 15, is GRANTED;

2. That Plaintiffs' Cross Motion for Partial Summary Judgment that the Patents-in-Suit Are Not Invalid, Paper No. 24, is DENIED;

3. That the parties are to submit to the Court a Joint Status Report on or before August 24, 2001; and

4. That the Clerk of this Court is to transmit this memorandum and order to all counsel of record.

s/ William M. Nickerson
William M. Nickerson
United States District Judge

Date: August 8, 2001

APPENDIX D

United States Court of Appeals,
Federal Circuit.

In re CRUCIFEROUS SPROUT LITIGATION.

Brassica Protection Products LLC and Johns Hopkins University,
Plaintiffs-Appellants,

v.

Sunrise Farms, Becky Crikelair, and Frank Crikelair,
Defendants-Appellees,

and

Edrich Farms Inc., Edward B. Stanfield, III, Edward F. Stanfield, Jr., Richard Stanfield, and Sally F. Stanfield,
Defendants-Appellees,

and

Banner Mountain Sprouts, Banner Mountain Sprouts Inc., and Lawrence Ravitz,
Defendants-Appellees,

and

Harmony Farms, Greg Lynn, and Lorna Lynn,

and

International Specialty Supply and Robert L. Rust,
Defendants-Appellees.

No. 02-1031

ORDER

A combined petition for panel rehearing en banc having

been filed by the APPELLANTS, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on October 7, 2002.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: September 30, 2002

cc: E. Anthony Figg
J. Kromholz, P. Andrews, D. Barnard, D. Ulrich

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

APPENDIX E

(Notice of Allowability for U.S. Patent No. 5,725,895)

UNITED STATES DEPARTMENT OF COMMERCE
Patent Trademark Office

Address
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/528,858	09/15/95	FAHEY J	46528/102

EXAMINER	
WONG, L	
ART UNIT	PAPER NUMBER
1302	13

DATE MAILED: 8/14/97

FOLEY & LARDNER
3000 K STREET, NW
SUITE 500
WASHINGTON, D.C. 20007-5109

NOTICE OF ALLOWABILITY

PART I.

1. ☒ This communication is responsive to papers filed 6/18/97.

2. ☒ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.

3. ☒ The allowed claims are 21-26, 28-34 and 36-38.

***

6. ☒ Note the attached Examiner's Amendment.

7. ☒ Note the attached Examiner Interview Summary Record, PTOL-413.

8. ☒ Note the attached Examiner's Statement for Reasons for Allowance.

***

Attachments:

☒ Examiner's Amendment

☒ Examiner Interview Summary, Record PTOL-413

☒ Reasons for Allowance

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

***

The following is an examiner's statement of reasons for allowance: a method of preparing a food product wherein cruciferous sprouts, with the exception of cabbage, cress, mustard, and radish sprouts are harvested prior to the 2-leaf stage is not taught nor fairly suggested by the prior art or any combination thereof.

***

s/Leslie Wong
Primary Examiner
Art Unit 1302

LAW
August 13, 1997

APPENDIX F

(Notice of Allowability for U.S. Patent No. 5,968,567)

NOTICE OF ALLOWABILITY	Application No. 08/840,234	Applicant(s) Fahey et al.
	Examiner Leslie Wong	Group Art Unit 1761

All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.

☒ This communication is responsive to papers filed 11/18/98 and 1/7/99.

☒ The allowed claim(s) is/are 69-90 (renumbered 1-22).

***

/s Leslie Wong
Leslie Wong
Primary Examiner
Group 1700
1/27/99

APPENDIX G

(Notice of Allowability for U.S. Patent No. 5,968,505)

NOTICE OF ALLOWABILITY	Application No. 08/997,813	Applicant(s) Fahey et al.
	Examiner Kimberly Jordan	Group Art Unit 1614

All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.

☒ This communication is responsive to Paper Nos. 8-9.

☒ The allowed claim(s) is/are 48-57, 68, 69, and 72-79.

***

/s Kimberly Jordan
Primary Examiner
Art Unit 1614

APPENDIX H

UNITED STATES DEPARTMENT OF COMMERCE
Patent Trademark Office

Address
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.
90/005,530	10/12/99	5725895	5121.02L

EXAMINER	
WONG, L	
ART UNIT	PAPER NUMBER
1761	11

DATE MAILED: 7/12/00

BERNARD D SAXE
FOLEY & LARDNER
3000 K STREET, NW SUITE 500
WASHINGTON, D.C. 20007-5109

NOTICE OF INTENT TO ISSUE REEXAMINATION CERTIFICATE

1. ☒ Examination has been terminated in this reexam proceeding and a Certificate will be issued in due course in view of:

   a. ☒ Patent owner's communication filed on: May 8, 2000.

***

2. ☒ Note attached statement of reasons for patentability and/or confirmation....

4. ☒ Note attached LIST OF REFERENCES CITED, PTO - 1449, which is part of this communication and serves as an acknowledgment of receipt of patent owner's

prior art statement. The references which were considered have been initialed on the form by the examiner and the claims are deemed patentable thereover.

Art Unit:

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding: a method of preparing a food product wherein cruciferous sprouts, with the exception of cabbage, cress, mustard, and radish sprouts, that are rich in glucosinolates or contain high levels of phase 2 inducer activity are harvested prior to the 2-leaf stage is not taught nor fairly suggested by the prior art or any combination thereof.

***

s/Leslie Wong
Primary Examiner
Art Unit 1302

LAW
June 29, 2000

APPENDIX I

U.S. Patent No. 5,725,895 Claims at Issue

1. A method of preparing a food product rich in glucosinolates, comprising germinating cruciferous seeds, with the exception of cabbage, cress, mustard and radish seeds, and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts.

2. The method according to claim 1, wherein said sprouts contain non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucose isolates.

3. The method according to claim 1, wherein said seeds are a Brassica oleracea selected from the group of varieties consisting of acephala, alboglabra, botrytis, costata, gemmifera, gongylodes, italica, medullosa, palmifolia, ramosa, sabauda, sabellica, and selensia.

4. The method according to claim 3, wherein said seeds are Brassica oleracea variety italica.

5. The method according to claim 3, wherein said seeds are Brassica oleracea variety botrytis.

6. The method according to claim 5, wherein said seeds are Brassica oleracea variety botrytis subvariety cauliflora.

9. A method of preparing a food product rich in glucosinolates, comprising germinating cruciferous seeds that produce sprouts having at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential when measured after 3-days of growth and which contain non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates, and harvesting sprouts prior to the 2-leaf stage to form a food product comprising a plurality of sprouts.

APPENDIX J

U.S. Patent No. 5,968,567 Claims at Issue

1. A method of preparing a human food product comprising cruciferous sprouts containing high Phase 2 enzyme-inducing potential and non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates, comprising the steps of:

(a) identifying seeds which produce said sprouts, with the exception of Brassica oleracea capitata, Lepidium sativum, Sinapis alba, Sinapis nigra, and Raphanus sativus sprouts;

(b) germinating said seeds; and

(c) harvesting said sprouts between the onset of germination up to and including the 2-leaf stage, to form a human food product comprising a plurality of said sprouts.

2. The method according to claim 1, wherein said sprouts are harvested 1 to 14 days post-germination and contain at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential when measured after 3-days of growth and non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates.

3. The method according to claim 1 or 2, wherein said seeds are a Brassica oleracea selected from the group of varieties consisting of acephala, alboglabra, botrytis, costata, gemnifera, gongylodes, italica, medullosa, palmifolia, ramosa, sabauda, sabellica, and selensia.

4. The method according to claim 3, wherein said seeds are Brassica oleracea variety italica.

5. The method according to claim 3, wherein said seeds are Brassica oleracea variety botrytis.

6. The method according to claim 5, wherein said seeds

are Brassica oleracea variety botrytis subvariety cauliflora.

7. The method according to claim 1, wherein said sprouts are substantially free of Phase 1 enzyme-inducing potential.

8. A human food product comprising cruciferous sprouts made according to the method of claim 1.

APPENDIX K

U.S. Patent No. 5,968,505 Claims at Issue

1. A method of increasing the chemoprotective amount of Phase 2 enzymes in a mammal, comprising the steps of:

(a) identifying seeds which produce cruciferous sprouts, with the exception of Brassica oleracea capitata, Lepidium sativum, Sinapis alba, Sinapis nigra, and Raphanus sativus sprouts, containing high Phase 2 enzyme-inducing potential and non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates;

(b) germinating said seeds;

(c) harvesting said sprouts between the onset of germination up to and including the 2-leaf stage to form a food product comprising a plurality of sprouts; and

(d) administering said food product, or a non-toxic extract of said food product, to said mammal.

16. A method of reducing the level of carcinogens in a mammal, comprising the steps of:

(a) identifying seeds which produce cruciferous sprouts, with the exception of Brassica oleracea capitata, Lepidium sativum, Sinapis alba, Sinapis nigra, and Raphanus sativus sprouts, containing high Phase 2 enzyme-inducing potential and non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates;

(b) germinating said seeds;

(c) harvesting said sprouts between the onset of germination up to and including the 2-leaf stage to form a food product comprising a plurality of sprouts; and

(d) administering said food product, or a non-toxic extract of said food product, to said mammal.

APPENDIX L

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 046585/0122

In re patent under reexamination of

U.S. 5,725,895

Jed W. FAHEY *et al.* Group Art Unit: 1761

Serial No. 90/005,530 Examiner: L. Wong

Filed: October 12, 1999

For: METHOD OF PREPARING A FOOD PRODUCT FROM CRUCIFEROUS SEEDS

DECLARATION OF JED W. FAHEY UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

I, Jed W. Fahey, being duly warned, hereby declare and say:

1. I am a citizen of the United States of America, and reside at 6704 Ridge Road, Eldersburg, Maryland 21784.

2. I am a faculty research associate in the Brassica Chemoprotection Laboratory in the Department of Pharmacology and Molecular Sciences at Johns Hopkins University School of Medicine. My resume and list of publications are appended hereto as **Appendix 1**.

3. I am a co-inventor of U.S. patent No. 5,725,895 ("the patent") which is the subject of a reexamination proceeding which has been accorded serial No. 90/005,530. In relation to the reexamination, I have reviewed an Official Action,

mailed April 6, 2000, and the prior art cited therein, and I make the following observations.

4. Dr. Paul Talalay and I determined that certain cruciferous sprouts prepared according to the methods claimed in the patent contain high levels of Phase 2 inducer activity. Induction of Phase 2 detoxication enzymes, such as glutathione transferases, epoxide hydrolase, NAD(P)H: quinone reductase and glucuronosyltransferases, provides protection against carcinogenesis, mutagenesis and various forms of oxidative- and electrophile-induced cell damage. Cruciferous sprouts prepared according to the claimed methods can provide over 100-fold higher levels of Phase 2 enzyme inducer activity than market stage cruciferous vegetables.

5. Phase 2 enzyme inducer activity was measured in the Hepa 1c1c7 murine hepatoma cells grown in 96-well microtiter plates according to the method of Prochaska *et al., Anal. Biochem.* 169: 328-336 (1988) and Prochaska *et al., Proc. Natl. Acad. Sci USA* 89: 2394-2398 (1992), as modified by Fahey *et al., Proc. Natl. Acad. Sci. USA* 94: 10367-10372 (1997), after adding exogenous myrosinase to the incubation mixture. (**Appendix 2**). One unit of Phase 2 inducer activity is defined as the amount that when added to cells in a single microtiter well, doubles the quinone reductase activity. As noted above, quinone reductase is a typical Phase 2 enzyme.

6. Using the highly efficient and quantitative methods described in paragraph 5 above, Dr. Talalay and I unexpectedly found that market stage cauliflower may contain as little as about 5,000 Units/g fresh wt Phase 2 enzyme inducer activity. In contrast, 3-day-old cauliflower sprouts have Phase 2 inducer potential as high as 560,000 Units/g fresh wt. The range of differences between market stage broccoli and broccoli sprouts is similarly as high as 100-fold. For example, a fresh market stage broccoli cultivar may have an inducer potential as low as about 11,000 Units/g fresh wt. of Phase 2 enzyme inducer activity while a very high 3-day-old

broccoli sprout may have an inducer potential of 769,000 Units/g fresh wt. as reported in Fahey *et al., Proc. Natl. Acad. Sci. USA* 94: 10367-10372 (1997) on page 10370, second column, second complete paragraph (**Appendix 2**). Certain cruciferous sprouts may contain substantial quantities of isothiocyanates, mostly in the form of their glucosinolate precursors. Some of these isothiocyanates, including sulforaphane or 4-methylsulfinylbutyl isothiocyanate, are strong inducers of Phase 2 enzymes. Sulforaphane and several synthetic acetylnorbornyl isothiocyanate analogues, which are potent Phase 2 enzyme inducers, reduced the incidence, multiplicity and weight of mammary tumors and retarded tumor development in female Sprague-Dawley rats treated with a single of dose of DMBA. Zhang *et al., Proc. Natl. Acad. Sci USA* 91: 2147-2150 (1994) (**Appendix 3**).

7. Importantly, not all cruciferous sprouts have high levels of Phase 2 enzyme inducer activity. Among those species of crucifers which do produce sprouts with high levels of Phase 2 inducer activity, not all plant selections or cultivars within a given species, have the high levels of inducer activity. As shown in **Appendix 4**, for example, randomly selected Brussels sprout cultivars did not produce 3-day-old sprouts that contain more than 200,000 Units/g fresh wt. of phase 2 enzyme inducer potential.

8. I determined the Phase 2 inducer activity in 3-day-old sprouts of 28 different and randomly selected commercial cultivars of broccoli (**Appendix 5**). The Phase 2 inducer activity in each of these cultivars ranged from as little as 10,000 to as high as 769,000 Units quinone reductase inducing potential activity per gram fresh weight. Among the cultivars tested, 46% produced 3-day-old sprouts which had 200,000 or fewer Units quinone reductase inducing activity per gram fresh weight.

9. I determined the Phase 2 inducer activity in 3-day-old sprouts of a number of randomly selected commercial culti-

vars of cauliflower. Phase 2 enzyme inducer activity was measured in the Hepa 1c1c7 murine hepatoma cell assay. The inducer potencies ranged from 50,000 to 560,000 Units quinone reductase inducing activity per gram fresh weight. These results are reported in Fahey *et al., Proc. Natl. Acad. Sci. USA* 94: 10367-10372 (1997) on page 10370, column 2, second complete paragraph (**Appendix 2**).

10. Likewise, the Phase 2 inducer activity in 3-day-old sprouts made from different kale cultivars ranged from less than 10,000 to greater than 200,000 Units quinone reductase inducing activity per gram fresh weight (**Appendix 6**).

11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

May 8, 2000	s/ Jed W. Fahey
Date	Jed W. Fahey